

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to disclose how and where "part of the shaft is replaced by spring, having circular or oblique or oblique spirals/strands to absorb and transmit forward force for balloon advancement while maintaining alignment" as recited in claim 22.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2.1. Claim 22 recites the limitation "the shaft" in line 1. There is insufficient antecedent basis for this limitation in the claim.
- 2.2. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards

as the invention. The claim recites "a balloon and a stent" in line 1, however, there is no further limitation to define "the stent" indicated in line 1. It is not clear if the applicant is claiming "a balloon catheter" or "a combination of a balloon catheter and a stent". Clarification is required.

2.3. Claim 23 recites the limitation "the stent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

2.4. Claim 23 recites the limitation "the proximal edge" in line 5. There is insufficient antecedent basis for this limitation in the claim.

2.5. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "a balloon catheter", however, there is no further limitation to define a catheter. It is not clear whether the applicant is positively claiming "a balloon catheter" or "a stent" or "a combination of a balloon catheter and a stent". Clarification is required.

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a balloon catheter with a shaft including a part of the shaft replaced by a spring must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Fig. 1 only shows the springs A and B adjacent to a non-descriptive illustration assumed to be a balloon. The drawings fail to show how the springs are connected to a shaft and the balloon to make a balloon catheter to absorb and transmit forward force for the balloon catheter advancement while maintaining alignment.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. 37 CFR 1.83(b) reads as follows:

**When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.**

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate

figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

1. The disclosure is objected to under 37 CFR 1.71, as being so incomprehensible as to preclude a reasonable search of the prior art by the examiner. For example, the following items are not understood: how the springs are connected to a shaft and a balloon to make a balloon catheter to absorb and transmit forward force for the balloon catheter advancement while maintaining alignment.

Applicant is required to submit an amendment which clarifies the disclosure so that the examiner may make a proper comparison of the invention with the prior art.

**Applicant should be careful not to introduce any new matter into the disclosure**  
(i.e., matter which is not supported by the disclosure as originally filed).

2. The amendment filed 8/11/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall

introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Fig. 1A-1C.

Applicant is required to **cancel the new matter as presented in Fig. 1A-1C as filed in paper 8/11/2008 in the reply to this Office Action.**

**Fig. 1A-1C as filed in paper 8/11/2008 in the reply to this Office Action should be removed from the "Replacement Sheet" (paper 9/17/2010).**

2. The amendment filed 9/17/2010 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Fig. 1 showing springs 3 and 4 on page 23 of 24 of the amendment 9/17/2010.

Applicant is required to **cancel the new matter as presented in Fig. 1 showing springs 3 and 4 (page 23 of 24 of paper 9/17/2010) in the reply to this Office Action.**

### ***Response to Arguments***

The previous "Non-Final Office Action" (paper 6/11/2010) was provided for the Applicant to have a chance to respond. The "Advisory Office Action" (paper 5/6/2010), the "Final Office Action" (paper 1/25/2010) and "Non-Final Office Action" (paper 6/9/2009) have been withdrawn.

Applicant has filed the same identical responses twice in papers 6/25/2010 and 6/7/2010. This double filings the same identical responses in two different papers at different dates resulted in the "Final Office Action" on 8/30/2010.

The applicant is reminded that only one response should be filed for a previously issued office action. A double filing of the same response on different dates will create confusion and incorrect entering of the response, such as the case of two identical responses filed at different dates (papers 6/25/2010 and 6/7/2010), which have resulted in significant delay of the prosecution process.

The new Exhibits and new Fig. 1 showing springs 3 and 4 are not originally disclosed in the specification and are therefore considered as new subject matter introduced to this application.

On page 15 of 24 of the "Remarks", the Applicant admitted that a PTCA guide wire, a fine electrical insulation wire like structure, a spring and aPVC pipe were used to test the concept of the present application. It has been clear the applicant has never made a balloon catheter as claimed and until the present time, the Applicant have not possessed any balloon catheter as claimed.

### ***Conclusion***

**The “Final Office Action” (paper 8/30/2010) and the “Advisory Action” (paper 9/15/2010) have been vacated.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 3773

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/

Primary Examiner, Art Unit 3773